Checklists for Applicants and Grantees

From the National Institute of Allergy and Infectious Diseases'
"All About Grants" Series

http://www.niaid.nih.gov/ncn/grants/

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Grants Checklists

Before You Begin

- Do I know the field and its literature well?
- Do I know what other projects in my field are being funded?
- Is the field overpopulated with researchers?
- Did I check the literature to make sure the project I'm considering has not been done before, or has been done and its methods judged inadequate?
- Did I brainstorm ideas with colleagues and mentors?
- Did I discuss my proposal with program staff in the appropriate Institute?
- Did I check to see if my idea matches any NIAID initiatives reflecting its high-priority areas?
- Do I know what resources and support my organization has, and what other support I'll need?
- Did I check with my institution's business office to see what deadlines they have?
- Am I giving myself plenty of time to write the application, at least three to six months?
- Have I considered asking a few of my senior colleagues to be on a mock review committee so that I can get ideas along with feedback on the concept, planning, and writing stages of my application?

Documentation

- Will I be doing human subjects research?
- Will I be using research animals?
- Will I be doing rDNA research?
- Will I be doing stem cell research?
- Will I be filling out a modular application?
- Are there any special requirements in the program announcement or request for applications?
- If planning on working with select agents, have I registered with either CDC or USDA?

New Applicant

- Have I checked the checkbox in the application face page so NIH and reviewers can readily identify me as a new applicant?
- Am I asking for less than $250,000?
- Am I following the instructions in the PHS 398 for a modular application?
- Have I balanced my lack of publications with more biographical information?
- Have I outlined modest, attainable goals that will match my level of experience?
- Have I shown that I have my own resources and institutional support, .am independent, and able to lead?
- Have I shown that I am independent and able to lead?
- Have I brought in (if possible, well-known) collaborators to fill gaps in my expertise and resources?
- Am I showing a solid understanding of the literature and a recognition of the strengths and weaknesses of my methods?
- Have I started preparing information to be sent "just in time"?

Hypothesis

- Is my proposal driven by a strong hypothesis?
- Have I defined what, specifically, I am setting out to prove?
- Is the central research question important to the field?
- Is the hypothesis testable by current methods?
- Did I state my hypothesis in the abstract and specific aims section?
- Is my idea focused enough? Is it provable during my three- to four-year award with the resources I am requesting?
- Does my topic fit with the NIH mission? Does it work towards improving health through science?

Research Plan

Planning

Answer these questions when you *develop* your research plan.

- Does my project address the review criteria?
- Does my research approach answer the question posed by my hypothesis?
- Does my project have a coherent direction?
- Are the aims of the project I am considering achievable?
- Does my project have a central focus?
- Have I kept myself from being *too* innovative? Can I justify my innovations with sound reasoning?
- Am I attempting a modest amount of work and not too much for my first research grant?
- Have I checked my project against common research problems that might keep me from getting funded?
- Have I familiarized myself with common review problems and solutions?

Process

Answer these questions when you *write* your research plan.

- Have I started with an outline, and then worked on developing each section?
- Am I presenting the information logically and clearly?
- Am I maintaining a balance between technical and nontechnical language in my writing?
- Am I keeping both of my audiences in mind (my primary reader and my other reviewers)?
- Am I highlighting the importance and innovation of my project?
- Am I following the exact format specified in the instructions?
- Am I explaining which gaps in science my project would fill?
- Am I referring to the literature thoroughly and thoughtfully?
- Did I state my hypothesis in the specific aims and abstract, and provide a logical rationale for the hypothesis?
- Did I prepare an appropriate budget, having checked the notices in the *NIH Guide* for any new requirements?
- Did I provide all necessary information for human subjects and animals?
- Did I include a timetable for the proposed research?
- Have I kept in mind the page length that the 398 recommends for sections a through d of my research plan?
- Have I followed the instructions in the PHS 398 to the letter?

Specific Aims

- Have I written this section in clear, nontechnical terms?
- Have I begun this section by stating the general purpose or objectives of my research?
- Have I limited myself to three or four specific aims?
- Do my specific aims and objectives support and test my hypothesis?
- Are they tightly focused?
- Did I present alternatives to my hypothesis and the reasons I chose the one I did?
- Can my objectives be assessed by the review committee?
- Did I list the experiments I'll do to support each aim?
- Did I mention what staff I'll need to accomplish my aims?
- Have I organized and defined my aims so I can relate them directly to my research methods?
- Have I kept in mind the page length that the PHS 398 recommends for this section?

Background and Significance

- Have I written this section in clear, nontechnical terms that all reviewers will understand?
- Did I show how my research is innovative?
- Did I explain why my project is worth funding?
- Have I conveyed the significance of my research and how it will increase knowledge in the field?
- Did I include background information about the field?
- Does the literature section show reviewers my understanding of the field?
- Have I shown that I know the gaps, discrepancies, or roadblocks in the field?
- Did I identify the next logical research beyond this application?
- Have I kept in mind the page length that the PHS 398 recommends for this section?

Preliminary Data

- Do the preliminary data support the hypothesis to be tested?
- Do they show the feasibility of the project?
- Did I focus on my own preliminary data, or when using results from other labs, draw a clear distinction between theirs and mine?
- Did I explain how the results from my preliminary studies are valid and how they will be expanded?
- Did I interpret my results critically and provide alternative meanings for them?
- Have I explained how my early work prepares me for the new project?
- Have I kept in mind the page length that the PHS 398 recommends for this section?

Design and Methods

General

- Does each experiment correspond to one of the specific aims, and are they stated in the same order?

- Do the experiments follow a logical sequence?
- Did I offer a timetable showing how and when I will accomplish my aims, including any overlap of experiments and alternative paths?
- Did I use flow charts and decision trees to show paths of experiments and how they will progress?
- Did I estimate what I expect to accomplish each year and state foreseeable delays?
- Did I describe any hazardous procedures, situations, or materials, as well as appropriate precautions?
- Did I include supporting data?
- Have I included sufficient detail to show I understand and can handle the research?
- Have I only included information that is needed to state my case, i.e., have I avoided including anything I don't plan to do?
- Does my appendix include publications showing my use of the methods I've described?
- Have I cited references wherever possible?

Approach

- Did I state the expected outcome of my research?
- Did I list each set of experiments in the same order as my specific aims, linking my experiements to the aims so reviewers can see how I will achieve them?
- Are the methods I chose appropriate to achieve the specific aims?
- Did I show why each experiment is important or how it is relevant to the hypothesis?
- Are the experiments in a logical sequence, flowing from one to another with clear end points?
- Did I offer a timeline for experiments?
- Will reviewers think I am knowledgeable about my methods?
- Did I justify my choice of methods in detail?
- Did I outline my methods in detail?
- Did I support my methods with data?
- Did I provide solutions for potential problems?
- Is my proposed model system appropriate?
- Did I address difficulties I may encounter with the proposed approaches, show I can handle them, and propose solutions and alternatives?
- Did I consider how the limitations of the approaches may affect my results and data?
- Did I address possible problems and limitations of the procedures, and propose solutions?
- Did I estimate how much I expect to accomplish each year of the grant and state any potential delays?
- Did I use enough detail?
- Did I include all relevant controls?
- Did I anticipate reviewers' questions about the feasibility of what I propose, e.g., how I will gain access to reagents, equipment, or study populations?

Results

- Did I show I am aware of the limits to and value of the kinds of results I expect?
- Have I convinced reviewers I will be able to interpret my results?

- Have I enlisted help from a statistician, if needed, and discussed statistical methods to be used?
- Did I define the criteria for evaluating the success or failure of a specific test?
- Did I state the conditions under which my experimental data would support or contradict my hypothesis?
- Did I state the limits I will observe in interpreting results?

Cited Literature

- Have I listed all publications supporting my hypothesis and methods?
- Have I formatted the citations correctly, i.e., the names of all authors (not *et al*.), name of the book or journal, volume number, page numbers (not first page only), and year of publication?

Abstract

- Did I stay within the 200-word limit?
- Did I state my hypothesis?
- Does my abstract describe my objectives and specific aims?
- Does it state the importance of the research and how it is innovative?
- Does it outline the methods I will use to accomplish my goals?
- Have I excluded all confidential or proprietary information from my abstract?
- Did I keep the language of my abstract simple and easy to understand for a broad audience?

Performance Site

- Have I listed all the sites where my work will take place?
- Does it match the information on the Resources Format Page?
- Have I included a Key Personnel header, listing all people involved and their roles? Does each have a biosketch?

Consultant

- Have I referred to consultants for any experience I lack?
- Have I tried to use consultants who are experts in their fields?
- Have I included in my application a letter describing the willingness of an investigator to participate as a consultant?
- Did I list my consultants as key personnel and provide biosketches in my application?

Biosketches

- Have I included biosketches in the proper order: principal investigator, then all others in alphabetical order by last name?
- Does each biosketch include all required details: name, title, education, and employment history?
- Does the employment history section contain dates, places, nature of position, professional experience, and honors in chronological order? Do these combined pieces of information adhere to the 2-page limit?
- Does my employment history contain a chronological list of relevant publications with titles and complete references (including all authors)?
- Are my roles in other relevant research included?

- Did I describe the aims of current and recent support?
- Have I kept in mind the page length that the PHS 398 recommends for this section?

Other Support

- Have I shown that no other organization is supporting the research I've outlined in my research plan?
- Have I let NIH know of any support I or any of my key personnel have as of the time I send in the other support information -- just in time -- not the time I applied?
- If applying for more than one grant, did I point out in my application and my cover letter that there's no overlap between them, and made sure the aims differ?
- Does my other support section have subheads -- active, pending, and overlap -- showing dates, granting organization name, funds, a one-sentence description of the project, and the percentage of my time spent on each award?
- Have I made sure that I'm not committing more than 100 percent effort to all my support?
- Have I entered "none" if I have no other support?
- Have I withheld sending in my other support information until asked for by the just in time notice?

Budget

- Is my budget realistic and appropriate for the project's aims and methods?
- Have I requested only enough money to do the work?
- Have I made sure none of my requests appear to be extravagant or include resources already available to me?
- Is the PI's salary less or equal to the current government cap?
- Did I prepare a modular budget (for grants under $250,000)?
- Have I followed the instructions on the modular budget format page in the PHS 398?
- Have I planned for the cost of the entire project?
- Have I figured all of my costs into my modular budget?
- Did I specify salaries and costs, rounded to $1,000, for consortium arrangements?
- Have I avoided asking for expensive equipment, unless I really need it?

Resources

- Does my description of resources show adequate equipment, space, and support staff to conduct the research?

Cover Letter

- Have I included a cover letter with my application?
- Does it include my application's title?
- Does it include a list of people who should not review my application and why?
- Does it state the different disciplines involved, if multidisciplinary?
- If applicable, does it state that the application is in response to a RFA or PA?

- If applicable, does it state that the application was previously submitted in response to an RFA or PA?
- If applicable, does it state that I've enclosed the required institute approval documentation for a grant over $500,000?

Requesting an Institute

- Have I talked to my program officer and done research on the Web about the scientific areas each IC funds to increase my chances of getting funded?
- Have I found out which institutes are appropriate for my application in terms of their subject matter and paylines?
- Have I contacted the program officer to see if these institutes might have a special interest in my application?
- Have I considered getting my application assigned to more than one institute to increase my chances of geting funded?

Request an Institute Review Group

- Did I call the scientific review administrator (SRA) for help in determining which study section is appropriate?
- In searching for a study section, did I look for familiar names, or if unable to find any, read their papers to see if their work is similar to my own?
- Have I requested an IRG or specific study sections that may be friendly to my type of research?
- Did I frame my request in positive terms, noting that a study section has several people interested in my area and qualified to judge my work?
- Did I refrain from suggesting specific reviewers?
- After being notified of the assignment, did I check the committee's roster on the Web?
- Have I contacted the SRA if there is any major problem with the committee (e.g. a conflict of interest)?

Writing

General

- Have I made sure that my business office has completed its part of the face page?
- Have I carefully read the instructions and followed the rules, such as those for page limitations and font size?
- Did I follow the format outlined in PHS 398?
- Is the writing clear and concise?
- Have I anticipated any questions reviewers might have, and supplied the necessary information to answer them?
- Have I kept the basic concepts and key ideas as nontechnical as possible?

Presentation of Information

- Does the application have a pleasing presentation, e.g., well-organized and sufficient white space to prevent crowding of information?
- Have I labeled all materials clearly so that reviewers can easily find information?
- Is the type clean and legible?

- Do I begin with basic ideas and move towards more complex ideas?
- Have I included bullets and lists to draw attention to key facts and create visual breaks?
- Have I included graphics that can help reviewers grasp information quickly and easily?
- Have I only included information that will photocopy well?
- Have I made sure that any colored or glossy materials are in the appendix?
- Have I put all other graphs and charts (not on glossy paper) in the research plan and *not* the appendix?
- Have I included five collated sets of all appendix material in the same package with the application, following all copies of the application?
- Does a cover letter accompany my application?
- Have I included a table of contents?

Mechanics

- Do my paragraphs contain only one major point each?
- Do I use short, basic sentences that average 20 words or less?
- Do I include transitions to show the relationship between my ideas, using words such as: furthermore, additionally, in other words, in another area, in contrast, following the same path, and moving to the next stage?
- Do I keep related ideas and information together, e.g., put clauses and phrases as close as possible to (preferably right after) the words they modify?
- Do I use strong, active verbs? Do I avoid passive verbs? (i.e. "We will develop a cell line," not "A cell line will be developed.")
- Do I use verbs instead of abstract nouns ending in "ion" and "ment"? (i.e. say "creating the assay leads to..." rather than "the creation of the assay leads to...")

Editing and Proofreading

- Have I edited and proofread the application thoroughly several times after giving myself a few days away from it to gain perspective?
- Have I eliminated redundant words and phrases?
- Have I checked all my information and data for consistency?
- Have I reviewed my conclusions to see if my supporting facts might lead a reader to different conclusions?
- Did I have several colleagues critique the application on the writing and presentation?
- Have I gotten editorial help from a nonscientist with a strong writing background?
- Have I supported all facts with citations?
- Have I avoided using URLs for source material in my application?
- Have I checked my table of contents to make sure that all the items and page numbers correspond to those in the body of my application?
- Have I stayed within the 56-character limit (including spaces) for the title of my project?

Revising

- Did I read the summary statement and identify the problems?
- Did I address reviewers' comments point by point, identifying changes clearly?
- Did I summarize substantial additions, deletions, and changes in three pages?

- Did I clearly distinguish sections that are the same in the previous application and those that are different, showing precisely where I added new information with a method that will show up on a photocopy (not changing the color of the text)?
- If I disagreed with the reviewers, did I explain why and provide additional information?
- Did I follow the instructions in PHS 398?
- Did I keep the title the same as it was the first time I submitted my application?
- Did I include a three-page introduction to the research plan as part of the application?
- Does the introduction respond to the reviewers' comments by describing how I have substantially changed the application and addressed the criticisms outlined in the summary statement?
- Does it include any new findings I have had since I sent in the initial application?

Just in Time Information

- Has my institution sent in my Other Support information?
- When working with human subjects...
- Has my institution filed for a Human Subjects Assurance?
- Has my institution sent in my Certification of IRB Approval?
- Has my institution sent certification of Human Subjects Education?
- When working with research animals...
- Has my institution filed for an Animal Welfare Assurance?
- Has my institution sent in my Certification of IACUC Approval?

Notice of Grant Award

- Has my institution contacted the Division of Financial Advisory Services to negotiate indirect cost rates?
- Has my institution submitted an 1199A Direct Deposit Form?
- Do I have a payment plan (such as Cashline or Smartlink) set up?

Before Beginning Research

- Have I read the Terms and Conditions?
- Do I know what actions I am allowed to take under expanded authorities?
- Do I know what actions require prior approval from NIH?
- Do I know what actions of mine will constitute a change in the scope of my project?
- Do I know what kind of prior notification and approval NIH needs for these actions?
- For research involving select agents, have I made certain that CDC or USDA has approved my registration before spending any funds?
- Do I know how long I am going to be funded?
- Do I know whether or not there are any restrictions placed on my award?

While Doing Research

- Have I been reading the *NIH Guide for Grants and Contracts* and the *Council News* newsletter to keep abreast of policy changes that might affect my grant?
- Do I have reasonable monthly expenditures?
- Am I pacing myself with my spending?
- Do I have any new inventions that need to be reported?
- Am I making sure my institution is sending out all of my required reports on time?
- Am I reading each year's notice of grant award to make sure no restrictions have been placed on my award?

Ongoing Reporting Requirements

General

- Is my institution submitting a 272 report at the end of every quarter?
- Is my institution submitting an annual financial status report (269/269A)?
- Is my institution submitting an annual application for continuation (2590)?
- Is my institution meeting its audit requirements?
- For human subjects research, am I getting annual re-certification of IRB approval?
- Have I checked to see what other human subjects reporting requirements NIH has?
- For research involving animals, am I getting re-certification of IACUC approval every three years?

Invention Reporting

- Has my institution fully disclosed any invention to NIAID within two months after the inventor provided disclosure to the organizational official?
- Does it include, in writing, the name of the inventor(s), a complete technical description and other information as required by CFR's Standard Patent Rights Clauses, 37 CFR 401.14(c)(1)?
- When applying for continuation, did I include a list of all inventions conceived or brought to practice during the preceding budget period, or certification that no inventions were made during the period?
- Has my institution submitted an annual "utilization report," if necessary?
- Has my institution submitted a final inventions statement and certification at the end of my award?

End of Project Period

- Has my institution submitted my financial status report?
- Has my institution submitted my final progress report (2590)?
- Has my institution submitted my final invention report?
- Will I keep my records accessible for three years after my project is finished?

Human Subjects Checklists

General

- Have I gone through the decision trees to make sure my research falls under the rubric of human subjects? Have I used the other decision trees?

- Have I read through the human subjects section of the PHS 398?
- Is my research exempt from some of the application and reporting requirements? (Research of fetuses, pregnant women, prisoners, or children is never exempt)
- Have I justified any exemption in the human subjects section of my research plan?
- Regardless of any exemptions, have I addressed the inclusion of women, minorities, and children in my application?
- Have I taken into account that my application is also being reviewed for risks to subjects, adequacy of protection against risks, potential benefits to the subjects and others, and importance of the knowledge to be gained?
- Have I made it clear to reviewers that I've thought through all issues and shown explicitly how I will comply with all regulations?
- Has my institution filed a human subjects assurance online with the Office for Human Research Protections?
- Have I made sure that my protocol includes everything required?
- Have I marked item four on the face page "yes" for human subjects research?

Planning a Human Subjects Application

- Have I carefully read the human subjects section of the PHS 398?
- Have I followed all of its instructions?
- Have I asked for help from my business office and experienced grantees?
- Have I checked the NIAID Clinical Terms of Award to see what institute-specific requirements I'll need to fulfill?
- Have I called an NIAID program officer or project officer for advice about the terms?
- Am I planning ahead for the populations I'll need to include in the application, and for the reporting I'll do after I get the award?
- Have I started the process of getting my IRB to certify my research plan?
- Have I discussed my data and safety monitoring plan with my program or project officer?

Human Subjects Documentation

- Does my application have a research plan, one that includes the protocol (if required by the division)?
- Does it include a data and safety monitoring plan (for clinical trials)?
- Does it include a targeted/planned enrollment table?
- If several institutions are involved, have I submitted written documentation that each institution's IRB or IEC approved the protocol? Have I included a copy of the approved informed consent document and shown the version number or dates for which it is valid?
- Have I sent NIAID full documentation from all IRBs or IECs (both national and local)?
- Have I included in my application a letter documenting that the investigators involved in human subjects research have been educated in research conduct? Does that letter include a list of key personnel, the title, and a one-sentence description of the training?
- Have I placed all of my human subjects documentation in the human subjects section (e.) of my research plan?

Human Subjects Research Plan

- Have I given this section a heading called "Human Subjects Research" and placed it after the "Design and Methods" section?
- Do I have a subsection describing how I will protect subjects from research risks?
- Do I have a subsection on the inclusion, analysis, and outreach for women?
- Do I have a subsection on the inclusion, analysis, and outreach for minorities?
- Do I have a subsection on the inclusion, analysis, and outreach for children, demonstrating the expertise to study children, suitability of my facilities, and how I will recruit enough children?
- Do I have a subsection on data and safety monitoring?
- Do I have a subsection on the detection of differences in the intervention effect for women and minorities (for NIH-defined phase III clinical trials only)?
- Have I described my method and criteria for selecting subjects, dates of enrollment, and outreach and retention plans?
- Have I stated how I will ensure adequate numbers of minorities, children, and both genders, including outreach mechanisms? Have I justified any exclusions?
- Have I built this information into the project design?
- Did I use the racial and ethnic categories defined in the PHS 398?
- Have I checked with my program officer or project officer to see if the NIAID division I'm applying to requires my protocol in the application?
- Have demonstrated that I've thought through all issues and shown explicitly how I will comply with all regulations?
- Have I clearly stated how I will include diverse groups and protect subjects from study-related risks?
- Have I described the benefits of my research to patients and public health?
- If it is appropriate to the research for some groups to be excluded or poorly represented, have I described the issue in terms of the study's size, disease characteristics, and feasibility of accruing subjects?
- For inclusion of children, have I included a plan or justification for not studying them unless there are scientific or ethical reasons for not doing so?
- If there are scientific reasons for examining minority groups abroad, have I designed studies to accommodate their participation and data analysis?
- Have I made sure that my collaborators have their assurances with OHRP in place if they're working with human subjects?
- Have I included a data sharing plan, if appropriate?

Data Sharing Plan

- If my application is requesting more than $500,000 in direct costs in any year, does it include a data sharing plan?
- If responding to an RFA or RFP, have I read the announcement carefully for instructions about my data sharing plan?
- Have I contacted my program officer at least six weeks before submitting my application to determine whether NIAID will accept my application?
- Did I discuss my data sharing plan with my program officer when I contacted him or her?
- Have I included a data sharing plan in the research design and methods section or explained why data sharing is not possible?
- Have I made sure I am complying with the privacy rule of the Health Insurance Portability and Accountability Act (HIPAA) by removing any

information that could be used to identify a human subject before sharing data?

Human Subjects Protocol

- Does my protocol include a study design?
- Does it include interventions?
- Does it include patient eligibility?
- Does it include criteria for excluding any populations?
- Does it include plans to manage side effects?
- Does it include plans to assess and report adverse events?
- Does it include plans to monitor the data and safety of the trials, pharmacy, and laboratory?

Data and Safety Monitoring Plan

- Have I discussed my data and safety monitoring plan with my program or project officer?
- Do I monitor trials to ensure safety and effectiveness and recommend their conclusion?
- Have I minimized risks to a practical extent?
- Does the degree of monitoring correspond to the level of risk?
- Does my data and safety monitoring plan provide an independent, objective review of the conduct of the research, interim safety and efficacy data, and progress towards achieving study goals?
- Does it cover policies and procedures for reporting adverse events to the IRB, NIH Office of Biotechnology Activities (for studies involving rDNA), and FDA?

Phase III Clinical Trials

- Have I addressed inclusion, depending on whether I expect clinically important differences in the intervention effect by gender, or between racial or ethnic subpopulations?
- Have I designed analyses that can reveal intervention differences between men and women and between minorities and non-minorities, or show that such differences do not exist?
- Do my plans provide for subset analyses? Have they been approved by my IRB with the final protocol?
- If prior studies offer no strong evidence for or against differential effects, are my sample size and analysis plans sufficient for a "valid" analysis (unbiased, but not necessarily with high statistical power) of possible differences in intervention effect between subgroups?
- If prior studies strongly support the existence of differential effects, does the sample size and analysis answer the primary question separately for men and women, and for each racial or ethnic subgroup?
- Do I have a data and safety monitoring board (DSMB)?
- Has NIAID appproved my DSMB?
- Did I send my program or project officer a description of the board, its charter or operating procedures (including proposed meeting schedule and plan for review of adverse events), roster, and CVs of all members? Did I include a sentence describing their research conduct training?

Target Study Enrollment

- Have I planned for the populations I'll need to include in the application?
- Have I planned for the reporting I'll do after I get the award?

IND or IDE Requirements

- Does my research involve a new medical intervention?
- Have I obtained an investigational new drug application (IND) or investigational device exemption (IDE) from FDA? Or does FDA consider my research exempt?
- Have I let NIAID know the name, institution, and address of the IND or IDE sponsor, date filed with FDA, IND or IDE number, written comments from FDA, and written responses to those comments?
- Have I included risk information from the investigator's brochure, a review of the published literature, or other credible sources?
- Have I notified NIAID if the FDA has put my study on hold, and sent NIAID copies of all correspondence with FDA, including documentation that the hold has been lifted?
- For interventions studies, have I obtained regulatory oversight by either FDA (under an IND or IDE) or the regulatory body of the country where the research is to be conducted?
- For a foreign regulatory body, have I sent NIAID written documentation from the regulatory body showing I am in compliance with local regulatory laws?
- Have I looked over the IND or IDE reporting requirements checklist?

rDNA Requirements

- Has my application been reviewed by the NIH rDNA advisory committee (RAC)?
- Have I then had it reviewed by my institutional biosafety committee, FDA, and my IRB?
- Did I send written documentation, including comments, of those reviews and approvals to NIAID?
- Have I had a public RAC review?
- Have I sent NIAID a copy of the letter from the Office of Biotechnology Activities either stating the protocol has been exempted from public review, or summarizing the RAC suggestions and PI response to the recommendations?
- Have I sent NIAID documentation of training in human subjects protection for all study staff responsible for design or conduct of the research?
- Have I looked over the rDNA reporting requirements checklist?

Before Enrolling Participants

- Has NIAID approved my protocol, IRB or IEC approval, data and safety monitoring plans, IND or IDE information, RAC approval, and training in research conduct?
- Have I addressed any concerns to their satisfaction?
- Has my IRB or IEC approved any changes to the protocol?

Revising a Human Subject Application

- Have I contacted my program or project officer to determine how to resolve any concerns the review group had?
- Have I resolved any problems or concerns reviewers had with my application?

Human Subjects Reporting Requirements

General

- Have I determined what the basic reporting requirements are for an NIH award?
- Am I collecting data during the award, including data for minority subgroups, to complete the inclusion enrollment report table?
- Have I completed the targeted/planned enrollment table form?
- Have I included the inclusion enrollment report table as part of my annual progress report?
- Am I getting re-certification of IRB approval every year of my award?

When to Report to Your Program or Project Officer

- Have I requested prior approval for any amendments or changes to the protocol before implementing them?
- Have I had a protocol termination?
- Have I had any changes in informed consent or IRB approval status?
- Have I had a temporary suspension or permanent termination of patient accrual?
- Have I had any other problems or issues that could affect participants?
- Have I had any reports to or communications with FDA?
- Have I included the inclusion enrollment report table as part of my annual progress report?

IRB and IEC

- Have I had all relevant IRBs and IECs review the protocol and analysis plans as often as specified (at least once a year and whenever changes occur in my procedures)?
- When sending NIAID documentation of IRB or IEC continuing reviews, have I included the following information for each investigative site: IRB or IEC registration number; OHRP federalwide assurance number for the site; IRB or IEC continuing review and approval; IRB or IEC approved consent form and protocol, each identified by version number, date, or both; and any documents related to protocol amendments, suspensions, or termination?
- Have I reported any changes in informed consent or IRB approval status to NIAID?
- Have I also sent my program or project officer a copy of my IRB letter of renewal, latest IRB- or IEC-approved protocol identified by version number or date, or my latest IRB- or IEC-approved informed consent document identified by version number and dates it is valid?

IND or IDE

- Am I notifying NIAID in writing if FDA places my study on hold?

- Are the IND and IDE sponsors notifying FDA about adverse events through safety reports? Are they providing copies to the NIAID program or project officer within 24 hours of FDA notification?
- Am I reporting other adverse events I document during the trial in my annual IND or IDE report?
- For seven-day IND telephone or fax reports or 15-day IND written reports, have I sent a copy to my program or project officer within 24 hours of FDA notification?
- For IND reports of adverse device effect, have I sent a copy to my program or project officer within 24 hours of FDA notification?

rDNA

- Have I sent NIAID an annual report, as well as reports of adverse events not included in expedited reports to the Office of Biotechnology Activities?
- Have I sent NIAID a copy of the continuing approval of my institutional biosafety committee?
- Have I sent NIAID inclusion enrollment reports and documentation about training in human subjects protection for new study staff, if applicable?

To find an NIAID program officer, see our Staff Contact lists.

See other tutorials on the All About Grants page.